EUROPEAN
COMMISSION

Brussels, 8.2.2018
C(2018)909 (final)

COMMISSION IMPLEMENTING DECISION

of 8.2.2018

on the renewal of the marketing authorisation for the medicinal product for human use "Xtandi - enzalutamide", granted by Decision C(2013)4019(final)

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Astellas Pharma Europe B.V., on 29 August 2017, under Article 14(2) of Regulation (EC) No 726/2004 with a view to the renewal of the marketing authorisation for the medicinal product "Xtandi - enzalutamide",

Having regard to the opinion of the European Medicines Agency, formulated on 14 December 2017 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "Xtandi - enzalutamide", entered in the Community register of medicinal products under number(s) EU/1/13/846 and authorised by Commission Decision C(2013)4019(final) of 21 June 2013, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2].

(2) The marketing authorisation which expires on 25 June 2018 should therefore be renewed.

(3) Decision C(2013)4019(final) should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(4) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2013)4019(final) should therefore be replaced.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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1 OJ L 136, 30.4.2004, p. 1.

2 OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2013)4019(final) of 21 June 2013 which expires on 25 June 2018 is renewed.

Article 2

Decision C(2013)4019(final) is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden, Nederland.

Done at Brussels, 8.2.2018

For the Commission

Xavier PRATS MONNÉ
Director-General